IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IDENIX PHARMACEUTICALS, INC., UNIVERSITA DEGLI STUDI DI CAGLIARI, CENTRE NATIONAL DE LA RECHERCHE SCIENTIFIQUE, and L' UNIVERSITE MONTPELLIER II,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 13-1987-LPS
GILEAD SCIENCES, INC. and GILEAD PHARMASSET LLC,	)	
Defendants.	)	

REPORT AND RECOMMENDATION

Presently pending in this patent infringement action is a motion (the "Motion") filed by Plaintiffs Idenix Pharmaceuticals, Inc. ("Idenix"), Universita Degli Studi di Cagliari ("U Cagliari"), Centre National de la Recherche Scientifique ("CNRS"), and L' Universite Montpellier II ("UMII") (collectively, "Plaintiffs"), seeking dismissal of various counterclaims filed by Defendants Gilead Sciences, Inc. and Gilead Pharmasset LLC ("Defendants"). For the reasons set forth below, the Court recommends that Plaintiffs' Motion be GRANTED without prejudice.

I. BACKGROUND

On December 1, 2013, Plaintiffs filed the instant suit against Defendants. (D.I. 1) In that suit, Plaintiffs sought: (1) a declaratory judgment that Defendants' planned sale and distribution of the drug sofosbuvir (a drug intended to treat the hepatitis C virus, or "HCV") will infringe Plaintiffs' United States Patent No. 7,608,600 ("the '600 patent); and (2) a declaration of interference under 25 U.S.C. § 291 ("Section 291") declaring that one or more claims of

Defendant Gilead Pharmasset LLC's United States Patent No. 8,415,322 ("the '322 patent") interfered with one or more claims of the '600 patent, that the claims of the '600 patent were invented first, and that the interfering claims of the '322 patent are invalid. (D.I. 1) Later on the same day, Plaintiffs Idenix and U Cagliari filed a second lawsuit against Defendant Gilead Sciences, Inc. in the District of Massachusetts. (D.I. 1, Civil Action No. 14-846-LPS-CJB) In that suit, these Plaintiffs sought a declaratory judgment that Gilead Sciences, Inc.'s planned sale and distribution of sofosbuvir (or drugs and compositions containing sofosbuvir) would infringe their United States Patent Nos. 6,914,054 ("the '054 patent") and 7,608,597 ("the '597 patent"). (*Id.*)

Defendants thereafter answered the Complaint in the instant case and, *inter alia*, asserted 11 counterclaims. (D.I. 9) Plaintiffs, in turn, filed the instant Motion on April 2, 2014. (D.I. 13) The Motion was referred to the Court for resolution by Chief Judge Leonard P. Stark on May 20, 2014, (D.I. 22), and the Court held oral argument on the Motion on August 14, 2014.

Certain of Defendants' 11 counterclaims remain at issue with regard to the instant Motion. Those are: (1) Counts 5-6, which assert counterclaims for a declaratory judgment of non-infringement and invalidity, respectively, of Idenix and U Cagliari's United States Patent No. 8,299,038 ("the '038 patent"); (2) Counts 7-8, which assert counterclaims for a declaratory judgment of non-infringement and invalidity, respectively, of Plaintiffs' United States Patent No. 7,662,798 ("the '798 patent"); (3) Count 10, which asserts a counterclaim for a declaratory judgment of invalidity of the '600 patent; and (4) Count 11, which asserts a counterclaim seeking a declaratory judgment, pursuant to Section 291, declaring that one or more claims of the '600 patent interfere with one or more claims of Gilead Pharmasset LLC's '322 patent and that the

interfering claims of the '600 patent are invalid. (*See* D.I. 9, 14; D.I. 57 (hereinafter, "Tr.") at 7-9)

The United States District Court for the District of Massachusetts later transferred to this Court the case in which Plaintiffs alleged infringement of the '054 patent and the '597 patent; that matter became Civil Action No. 14-846-LPS-CJB in this District. (D.I. 39, Civil Action No. 14-846-LPS-CJB) It was consolidated for scheduling purposes with the instant case and a third case, Civil Action No. 14-109-LPS (a case in which Plaintiffs brought an action against Defendant Gilead Pharmasset LLC challenging a decision of the Patent Trial and Appeal Board of the United States Patent and Trademark Office ("PTO"), pursuant to 25 U.S.C. § 146, regarding a related interference action). (D.I. 42; D.I. 1, Civil Action No. 14-109-LPS) The transfer of now Civil Action No. 14-846-LPS-CJB has mooted some arguments previously pressed by Plaintiffs in the Motion, but the remaining issues are ripe for resolution.[1]

II. DISCUSSION

The parties have three separate remaining disputes that implicate the Counts referenced above, which the Court will address in turn.

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[1] In the Motion as originally filed, Plaintiffs sought transfer of Counts 1-6 to the District of Massachusetts, or a stay of the instant action until the District of Massachusetts decided the transfer motion before it. (D.I. 13, 14) In light of the District of Massachusetts' transfer of that action to this Court, those portions of the instant Motion have been mooted, (D.I. 29), and the Court will not address them here. Additionally, the Motion originally sought dismissal of Counts 1-4, which asserted counterclaims of noninfringement and invalidity as to the '054 patent and the '597 patent, respectively. (D.I. 9 at 21-23 at ¶¶ 58-75; D.I. 13, 14) At oral argument, the parties informed the Court that this portion of the Motion had also been rendered moot by Defendants' agreement to dismiss those counterclaims, without prejudice to their ability to re-file them as counterclaims in Civil Action No. 14-846-LPS-CJB. (Tr. at 7-9) In light of those representations, the Court will also not address the issues raised in the briefs relating to Counts 1-4.

A. Whether Counts 5-8 Should Be Dismissed For Lack of Subject Matter Jurisdiction

Plaintiffs assert that Counts 5-8 (involving counterclaims seeking a declaratory judgment of non-infringement and invalidity of the '038 patent and the '798 patent, respectively) should be dismissed for lack of subject matter jurisdiction, pursuant to Federal Rule of Civil Procedure 12(b)(1). (D.I. 14 at 13-16; D.I. 19 at 6-8)

In assessing a factual attack to subject matter jurisdiction, such as this one, the reviewing court is not confined to the allegations in the complaint, but instead can consider affidavits, depositions, testimony and other similar evidence in order to resolve factual issues bearing on jurisdiction. *Gotha v. United States*, 115 F.3d 176, 179 (3d Cir. 1997); *Nexans Inc. v. Belden Inc.*, 966 F. Supp. 2d. 396, 401 (D. Del. 2013). In such a situation, no presumption of truthfulness attaches to the allegations, and the existence of disputed material facts will not preclude a trial court from evaluating for itself the merits of jurisdictional claims. *Nexans Inc.*, 966 F. Supp. 2d. at 401.

The Declaratory Judgment Act requires that a "case of actual controversy" exist between the parties before a federal court may exercise jurisdiction. 28 U.S.C. § 2201(a). In determining whether there is subject matter jurisdiction over declaratory judgment claims, a court should ask "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (internal quotation marks and citation omitted) (noting that the Declaratory Judgment Act's requirement that a "'case of actual controversy'" exist is a reference to the types

of cases and controversies that are justiciable under Article III); *see also Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1334 (Fed. Cir. 2008). A case or controversy must be "based on a *real* and *immediate* injury or threat of future injury that is *caused by the* [counterclaim] *defendants*—an objective standard that cannot be met by a purely subjective or speculative fear of future harm." *Prasco, LLC*, 537 F.3d at 1339 (emphasis in original). Thus, in the patent context, "jurisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, without some affirmative act by the patentee." *Id.* (internal quotation marks and citation omitted).

A decision as to whether an actual controversy exists in the context of a patent declaratory judgment claim "will necessarily be fact specific and must be made in consideration of all the relevant circumstances." *W.L. Gore & Assocs., Inc. v. AGA Med. Corp.*, Civil No. 11-539 (JBS-KMW), 2012 WL 924978, at *4 (D. Del. Mar. 19, 2012) (citing *MedImmune, Inc.*, 549 U.S. at 127). The burden is on the party asserting declaratory judgment jurisdiction (here, Defendants) to establish the existence of an Article III case or controversy. *Danisco U.S. Inc. v. Novozymes A/S*, 744 F.3d 1325, 1329 (Fed. Cir. 2014); *Butamax Advanced Biofuels LLC v. Gevo, Inc.*, Civ. No. 12-1301-SLR, 2013 WL 1856308, at *2 (D. Del. May 2, 2013).

After reviewing the particularized facts at issue as to Counts 5-8, the Court concludes that Defendants have not met that burden. In so concluding, the Court nevertheless acknowledges that the issue is a close one.

This is in part because Defendants can point to a number of facts that raise understandable concern as to whether they might face further suit from Plaintiffs—at least as to

patents addressed to the general subject matter at issue in these cases. Indeed, it seems fairly clear from the record that, at the time of the filling of the counterclaims, Plaintiffs and Defendants had been engaged in litigation around the globe, regarding the general subject matter of patents and products involving 2'-modified nucleosides relevant to the treatment of HCV infection. (D.I. 9 at 16 at ¶ 37; D.I. 17 at 14) These have included pending litigations in Norway, Canada and Australia, as well as the two infringement suits recently filed by Plaintiffs that are now consolidated in this Court. (D.I. 9 at 16 at ¶ 37) It is thus not a stretch to say, as Defendants do, (D.I. 17 at 15), that "the parties have plainly been at war over patents involving [the same general subject matter implicated by the declaratory judgment claims] and are likely to be for the foreseeable future." *Danisco U.S. Inc.*, 744 F.3d at 1331 (noting that a history of patent litigation between the same parties involving related technologies, products and patents is a circumstance to be considered in assessing whether subject matter jurisdiction exists); *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1344 (Fed. Cir. 2007) (same)

Defendants' position is also supported by the fact that there are a number of undeniable similarities between the '038 and '798 patents on the one hand, and the patents Plaintiffs have asserted in the consolidated actions on the other. *Cf. Nexans Inc.*, 966 F. Supp. 2d. at 401 (finding fact that patent at issue shared "the same title, the same inventors, and substantially the same specification" with another patent that was decidedly in dispute between the parties, weighed in favor of a finding of subject matter jurisdiction). For example, the '038 patent is a continuation of the application that issued as the '597 patent, which in turn is a continuation of the application that issued as the '054 patent. (D.I. 9 at 13 at ¶ 15 & ex. C) The '038, '597 and '054 patents all possess the same title and the same inventors, share substantially the same

specification, and all address the same general subject matter—methods and compositions for treating a host infected with HCV by administering an amount of described 1', 2', or 3'-modified nucleoside or a pharmaceutically acceptable salt or prodrug thereof. (D.I. 9 at 12 at ¶¶ 7, 10, 14 & exs. A-C; D.I. 17 at 15) Additionally, Idenix filed a terminal disclaimer over the '597 and '054 patents during prosecution of the '038 patent. (D.I. 9 at 13 at ¶ 15 & exs. A-C; D.I. 17 at 15)[2] As to the '798 patent, both it and the '600 patent share some inventors and both are directed to the same general subject matter—2' and/or 3' prodrugs of 1', 2', 3' or 4'-branched nucleosides, and their pharmaceutically acceptable salts and derivatives, useful in preventing and treating *Flaviviridae* infections (such as HCV). (D.I. 1, ex. A; D.I. 9 at 13 at ¶¶ 17, 21 & ex. D; D.I. 17 at 15-16) Idenix also filed a terminal disclaimer over the '054 patent during prosecution of the '798 patent. (D.I. 17 at 16; *see also* D.I. 9 at 13 at ¶ 20)[3]

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[2] *But see Ventana Med. Sys., Inc. v. Biogenex Labs., Inc.*, 473 F.3d 1173, 1184 n.4 (Fed. Cir. 2006) (noting that the filing of a terminal disclaimer does not constitute an admission by the inventors equating all claims of the patent at issue to the claims of the patent that it was disclaimed over) (citing *Quad Envtl. Techs. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 874 (Fed. Cir. 1991)).

[3] Defendants also note that, subsequent to the initiation of this litigation and the filing of their counterclaims, they sought assurances from Idenix that it would not sue Defendants for infringement of the '038 and '798 patents—in the form of an agreement by which Defendants would dismiss counterclaims 5-8 in exchange for a covenant not to sue from Idenix. (D.I. 17 at 16-17; D.I. 18, ex. 9-10) Idenix declined, asserting that any such assurances were unnecessary. (D.I. 18, ex. 11) The Federal Circuit has noted that "although a patentee's refusal to give assurances that it will not enforce its patent is relevant to the determination [regarding subject matter jurisdiction at issue here], it is not dispositive." *Prasco, LLC*, 537 F.3d at 1341 (internal quotation marks and citation omitted). Moreover, the Federal Circuit has questioned how and whether "post-complaint facts" like these should be considered as a factor that strengthens the case for subject matter jurisdiction, in light of the fact that "[a] declaratory judgment plaintiff must plead facts sufficient to establish jurisdiction at the time of the complaint[.]" *Microsoft Corp. v. Datatern, Inc.*, 755 F.3d 899, 906 (Fed. Cir. 2014). The Court assumes that, as is the case in a standing inquiry, a post-complaint (or post-counterclaim) act, such as the signing of a covenant not to sue, might be sufficient to defeat a claim that a case or controversy existed (if the

And yet, Plaintiffs also can point to significant facts in support of their Motion. Perhaps first among these is that, as to the '038 and '798 patents *in particular*, Plaintiffs have never taken any steps to threaten Defendants with litigation. It is not disputed that Plaintiffs have never sued Defendants (or any party) as to those patents, have never directly threatened Defendants with such a suit, and had never otherwise communicated with Defendants regarding those patents prior to Defendants' filing of the counterclaims here. (D.I. 14 at 14-16; Tr. at 10) While not dispositive, *see Danisco*, 744 F.3d at 1330, these facts are not insignificant, either. *See, e.g., Quantum Loyalty Sys. Inc. v. TPG Rewards Inc.*, Civil Action No. 09-22-RGA, 2012 WL 1134779, at *1 (D. Del. Apr. 4, 2012) (finding no declaratory judgment jurisdiction as to "two related patents with the same specification" and the same title as the patent on which plaintiffs sued, where the patent holder had not pressed the two related patents in litigation); *W.L. Gore & Assocs., Inc.*, 2012 WL 924978, at *6 (finding no declaratory judgment jurisdiction in a case where the patent at issue "'relates to similar technology as'" a patent currently in litigation between the parties, and where the patent holder had marked its own products with the patent at issue, in significant part because the patent holder had never asserted the patent at issue against the claimant, nor threatened to do so) (citation omitted); *see also Prasco, LLC*, 537 F.3d at 1340-

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act fully negated the underlying injury). *Cf. Prasco, LLC*, 537 F.3d at 1341 n.11. And it may be that a post-complaint act (or failure to act) could further bolster the case for subject matter jurisdiction, if jurisdiction otherwise existed at the time of suit. But regardless, it is quite clear that the "refusal to grant a covenant not to sue is not sufficient to create an actual controversy [where one does not otherwise exist] because a patentee has no obligation . . . to make a definitive determination, at the time and place of the competitors' choosing, that it will never bring an infringement suit." *Microsoft Corp.*, 755 F.3d at 906 (internal quotation marks and citation omitted). And since the Court's ultimate decision here is that Defendants have not demonstrated that subject matter jurisdiction existed as to Counts 5-8 at the time of the filing of the counterclaims, the post-filing, covenant-related activity between the parties does not affect the Court's calculus.

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Additionally, Plaintiffs can also point to noticeable differences between the '038 and '798 patents on the one hand, and the patents Plaintiffs have asserted in these consolidated cases on the other. The '798 patent, for example, arises from a different patent family than the '600, the '054 and the '597 patents, and has a different prosecution history and a different specification than those other patents. (D.I. 19 at 8) Additionally, the claims of the '038 and '798 patents, while similar in some respects, are obviously also different in some ways from the claims of the '600, the '054 and the '597 patents. And these respective claims are different in ways that make it hard to tell, simply by reading them, whether a claim of infringement as to the '600, the '054 or the '597 patents might inexorably suggest that a claim of infringement as to the '038 and '798 patents is close at hand.[4] Here, in comparing the claims of the '038 patent and the '054 and the '597 patents, for example, the claims appear to cover methods of treating HCV through the use of nucleoside compounds that largely have different chemical formulas or structures. (D.I. 9, exs. A-C; Tr. at 34, 41-42) A comparison of the claims of the '798 patent and the '600 patent shows the same. (D.I. 1, ex. A; D.I. 9, ex. D) And without more in the record than there is here, the Court cannot assertively conclude that these differences (and what they might mean when compared, in turn, with the chemical structure of sofosbuvir) are of a kind that nevertheless renders the threat of future suit as to the '038 and '798 patents real and immediate.

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[4] *Cf. Butamax Advanced Biofuels LLC*, 2013 WL 1856308, at *2 (finding declaratory judgment jurisdiction existed due to a number of factors, such as a history of litigation between the parties as to the subject matter of the patent at issue, and because the patent at issue was a continuation of and shared the same specification with a patent previously litigated by the parties—but also notably because, in comparing the claims of the patent at issue and the previously-litigated patent, this Court was convinced that there were "substantial similarities in the claimed subject matter").

In the end, this close decision is swung by two primary factors. The first is that in nearly all of the key patent cases cited by the parties in which courts have found subject matter jurisdiction to exist regarding a declaratory judgment claim, the patent holder took far clearer, hostile action related to the patent at issue than have Plaintiffs here.[5] And the second is the nature of the burden—it is Defendants' burden to convince the Court why, though they have never been threatened with litigation over these two patents, circumstances suggest an imminent

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[5] *See, e.g.*, *Danisco*, 744 F.3d at 1331-32 (finding jurisdiction to exist, *inter alia*, where record demonstrated that patent holder sought the patent "because it believed that [claimant's] products would infringe once the claim issued" and "with the hopes of asserting it against" claimant's products, and also where the patent holder insisted on multiple occasions that the patent at issue read on and claimed a compound that was the active compound in the claimant's identified products); *Arris Grp., Inc. v. British Telecommc'ns, PLC*, 639 F.3d 1368, 1376-77 (Fed. Cir. 2011) (finding jurisdiction to exist, *inter alia*, where the patentee had accused claimant's customer of direct infringement of the patents at issue, had singled out the customer's use of the claimant's products in making those allegations, and where the claimant was directly involved in its customer's licensing negotiations with the patent holder in which the claimant and the patent holder exchanged infringement and non-infringement arguments regarding the patents at issue); *Teva Pharms. USA, Inc.*, 482 F.3d at 1340-41 (finding jurisdiction to exist in an Abbreviated New Drug Application ("ANDA") case where, *inter alia*, the patent holder listed the patents at issue in the Orange Book as covering the drug at issue, the claimant later certified that the listed patents were invalid under paragraph IV, and the patent holder thereafter sued claimant on another patent that was listed in the Orange Book with the patents at issue); *Plumtree Software, Inc. v. Datamize, LLC*, 473 F.3d 1152, 1156, 1159-60 (Fed. Cir. 2006) (finding jurisdiction to exist, *inter alia*, where the patentee had previously sent a letter to the claimant stating that it believed the claimant will infringe the claims of an application that later issued as one of the patents at issue, and where the patentee later directly stated its belief that claimant was infringing both of the patents at issue); *Nexans Inc.*, 966 F. Supp. 2d at 402 (finding jurisdiction to exist, *inter alia*, where patentee sent a warning letter to the claimant making an infringement allegation, and later stated that the patent at issue could fall into a group covering the claimant's products); *Network Video Techs., Inc. v. Nitek Int'l, LLC*, No. C 08-2208 MHP, 2008 WL 4679541, at *6 (N.D. Cal. Oct. 21, 2008) (finding jurisdiction to exist, *inter alia*, where the patent holder announced the issuance of the patent at issue, and then attempted to extract patent royalties from the claimant in exchange for a license to the patent at issue); *Tuthill Corp. v. ArvinMeritor, Inc.*, No. 07 C 2758, 2008 WL 4200888, at *5 (N.D. Ill. Sept. 5, 2008) (finding jurisdiction to exist, *inter alia*, where the patent holder sent a letter to the claimant, stating that it believed the claimant's product fell within the scope of the patents at issue, and warning that it was prepared to take subsequent legal action).

and real threat in the future. For the reasons expressed above (particularly with regard to addressing the differences among the patent claims at issue), Defendants have not sufficiently done so here.

Thus, the Court recommends that Plaintiffs' Motion as to Counts 5-8 be GRANTED.

B. Whether Counts 6, 8 and 10 Were Improperly Pled and Should Be Dismissed

Next, Plaintiffs assert that Counts 6, 8, and 10 should be dismissed. Plaintiffs argue that each of these counterclaims (which seek a declaration of invalidity regarding certain of the patents discussed above) contain only "bare-bones allegations" that are insufficient to meet the requirements of Rule 8(a) as articulated in *Twombly*, *Iqbal* and their progeny. (D.I. 14 at 16-17; D.I. 19 at 8-10)

Rule 8(a) requires "a short and plain statement of the claim showing that the pleader is entitled to relief[.]" Fed. R. Civ. P. 8(a)(2). Additionally, courts use the same standard in ruling on a motion to dismiss a counterclaim under Rule 12(b)(6) as they do in assessing a claim in a complaint. *Tyco Fire Prods. LP v. Victaulic Co.*, 777 F. Supp. 2d 893, 898-99 (E.D. Pa. 2011) (citing cases). When presented with a Rule 12(b)(6) motion to dismiss for failure to state a claim, a court conducts a two-part analysis. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). First, the court separates the factual and legal elements of a claim, accepting "all of the complaint's well-pleaded facts as true, but [disregarding] any legal conclusions." *Id.* at 210-11. Second, the court determines "whether the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Id.* at 211 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the

misconduct alleged." *Iqbal*, 556 U.S. at 678 (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556 (2007)). In assessing the plausibility of a claim, the court must "construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Fowler*, 578 F.3d at 210 (citing *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)).

Defendants respond first by asserting that the *Twombly/Iqbal* pleading standard does not apply to patent counterclaims like these. In so doing, they rely on the reasoning of a line of cases suggesting the same, including *Bayer CropScience AG v. Dow AgroSciences LLC*, Civil No. 10-1045 RMB/JS, 2011 WL 6934557, at *2-3 (D. Del. Dec. 30, 2011) (citing cases). (D.I. 17 at 17-18)

However, the Court agrees with the contrary opinion expressed in *Senju Pharm. Co., Ltd. v. Apotex, Inc.*, 921 F. Supp. 2d 297 (D. Del. 2013). In *Senju*, this Court noted that other district courts concluding that invalidity counterclaims were not subject to *Twombly* and *Iqbal* tended to do so for two reasons, which were ultimately unpersuasive. *Senju*, 921 F. Supp. 2d at 302. The first reason often cited was that holding such counterclaims to the *Twombly/Iqbal* standard would "render [the particular district court's] local patent rules on the pleading standard for invalidity counterclaims superfluous[.]" *Id.* (citing cases). But the *Senju* Court noted that the District of Delaware has not adopted any local patent rules regarding the pleading standard for invalidity counterclaims, nor has it otherwise required that factual contentions be served promptly after a counterclaim of invalidity is advanced. *Id.* at 302-03.[6] The second oft-cited reason was that

[6] Moreover, even if this Court had adopted local patent rules, the content of such rules could not modify the pleading standard for counterclaims set out in the Federal Rules of Civil Procedure. *See Tyco Fire Prods. LP*, 777 F. Supp. 2d at 904 (citing Fed. R. Civ. P.

applying the *Twombly/Iqbal* pleading standard to these counterclaims would be "inequitable to defendants[,] in that it would impose on them a higher pleading burden than the Form 18 pleading burden on patent plaintiffs [applicable to such plaintiffs' claims of direct patent infringement]." *Id.* at 302 (citing cases). But the *Senju* Court pointed out that the Federal Circuit had emphasized that "'Form 18 [in the Appendix to the Federal Rules of Civil Procedure] should be strictly construed as measuring only the sufficiency of allegations of direct infringement[,]'" such that "the fact that Form 18 (rather than *Twombly* and *Iqbal*) remains the standard for pleading infringement claims is an insufficient justification for deviating from *Twombly* and *Iqbal* for pleading other causes of action." *Id.* at 303 (quoting *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1336 (Fed. Cir. 2012)).[7] For the reasons set out in *Senju* (and the others referenced in this subsection), the Court determines that Defendants' invalidity-related counterclaims are subject to the requirements of *Twombly* and *Iqbal*. *See also*

83(a)(1)); *see also Whitserve, LLC v. GoDaddy.com*, Civil Action No. 3:11-CV-948 (JCH), 2011 WL 5825712, at *2 n.2 (D. Conn. Nov. 17, 2011) (same).

[7] In *In re Bill of Lading*, cited by the *Senju* Court, the Federal Circuit explained that "to the extent [that] . . . *Twombly* and its progeny conflict with the Forms [e.g., Form 18] and create different pleading[] requirements, the Forms control." *In re Bill of Lading*, 681 F.3d at 1334. However, the Federal Circuit's conclusion there was particular to a claim governed by one of the Forms, because Federal Rule of Civil Procedure 84 makes clear that "a pleading . . . that follows one of the Official Forms cannot be successfully attacked" and because the Supreme Court has noted that any changes to the Federal Rules cannot be made by "judicial interpretation." *Id.* (internal quotation marks and citations omitted). Thus, when it comes to a "patent invalidity [counter]claim[,]" whose sufficiency is not clearly covered by one of these Forms, "there is no legal basis for [a] court to ignore the clear mandates of the Supreme Court [in *Twombly* and *Iqbal*,] even though the result is a disparate pleading burden between a patentee [pleading a patent infringement claim] and an accused infringer" pleading an "invalidity counterclaim[.]" *Gemcor II, LLC v. Electroimpact Inc.*, No. 11-CV-2520-CM, 2012 WL 628199, at *2 (D. Kan. Feb. 27, 2012); *see also Memory Control Enter., LLC v. Edmunds.com, Inc.*, No. CV 11-7658 PA (JCx), 2012 WL 681765, at *3 (C.D. Cal. Feb. 8, 2012).

EMC Corp. v. Zerto, Inc., C.A. No. 12-956-GMS, 2014 WL 3809365, at *2 (D. Del. July 31, 2014) (agreeing with the *Senju* Court's reasoning and concluding that counterclaims of invalidity must satisfy the *Twombly* and *Iqbal* pleading standard).

Defendants next assert that even if the *Twombly/Iqbal* pleading standard applies to these counterclaims, that standard has been met here. (D.I. 17 at 18-19) The Court again disagrees.

In the first instance, the relevant portions of the Counts themselves simply assert that the "claims of the [patent at issue] are invalid for failure to comply with one or more provisions of Title 35 of the United States Code related to patentability, including but not limited to, 35 U.S.C. §§ 101, 102, 103, and 112 . . . ." (*See, e.g.*, D.I. 9 at 22 at ¶ 65) These are "bare-bones legal conclusions devoid of any supporting factual allegations" that are insufficient to meet the *Twombly/Iqbal* standard. *EMC Corp.*, 2014 WL 3809365, at *2 (concluding this as to similarly-phrased invalidity counterclaims); *see also Senju*, 921 F. Supp. 2d at 303 (same). Although "counterclaims of invalidity do not need detailed factual allegations[,]" they need to, at a minimum, not only provide notice of what particular type of claims of invalidity are at issue, but also bolster those allegations with at least enough "supporting factual allegations" to render the claims plausible. *EMC Corp.*, 2014 WL 3809365, at *2.

Defendants further suggest that the *Twombly/Iqbal* standard is met because their counterclaims "contain 57 paragraphs of factual allegations describing the parties, the patents-in-suit, sofosbuvir, Idenix's patents and the related nature of those patents" and that certain of the counterclaims' allegations make reference to invalidity arguments that Gilead Pharmasset LLC either raised or suggested it would raise to the PTO in the two prior interference proceedings involving it and Idenix. (D.I. 17 at 19) Yet other than the few paragraphs that reference the prior

interference proceedings, none of the rest of these 57 paragraphs in the Counterclaims state, or really even hint at, a particular type of invalidity counterclaim (let alone facts that might make such a claim plausible).

As to the paragraphs referencing the prior interference proceedings, the Court finds the references to be too ambiguous for these purposes. (*See* D.I. 9 at 18-21 at ¶¶ 45-57) That is, even after reviewing the paragraphs (and the attached exhibits from the PTO interference proceedings that are cited therein) the Court cannot clearly discern what types of invalidity counterclaims Defendants attempt to assert *in this case* as to *the particular patents referenced in Counts 6, 8 and 10*. In part, this is due to the fact that the two referenced interference proceedings did not involve at least the two patents at issue in Counts 6 and 8 (the '038 patent and the '798 patent). With regard to the '600 patent (at issue in Count 10), it is true that: (1) the first and second interference proceedings involved, respectively, a related application to the patent and the patent itself, (D.I. 9 at 19-21 at ¶¶ 51, 57); and (2) the Counterclaims do make fleeting reference to "motions" that Gilead Pharmasset LLC filed or intended to file in those interference proceedings (motions that, although one could not tell it from the wording of the Counterclaims, involved, *inter alia*, claims pursuant to 35 U.S.C. §§ 101, 102, 103 and 112), (*id.*; *see also* Tr. at 74-79). But even so, these paragraphs do not amount to clear, affirmative statements regarding the nature of the invalidity-related arguments Defendants intend to press *in this case* against Plaintiffs as to *this* patent-in-suit.

Ultimately, in reading these paragraphs, it is not clear at all that their reason for inclusion is to put Plaintiffs on notice of the type of invalidity counterclaims they face here (or what the facts relevant to those claims are). In the absence of this type of clarity, Plaintiffs and the Court

are left to guess as to what Counts 6, 8 and 10 are meant to put at issue and why. *Twombly* and *Iqbal* do not sanction the need for such guesswork.

The Court's decision is not in conflict with that in *Joao Bock Transaction Sys., LLC v. Jack Henry & Assocs., Inc.*, 292 F.R.D. 167 (D. Del. 2013), a case cited by both parties. (D.I. 17 at 19; D.I. 19 at 8 n.3) In *Joao Bock*, this Court found that a defendant's counterclaim, which, *inter alia*, sought a declaratory judgment that the patent-in-suit ("the '003 patent") was invalid, provided sufficient detail to give rise to a plausible claim for relief. *Joao Bock*, 292 F.R.D. at 170. Although the counterclaim at issue asserted little more than that the '003 patent was invalid, it also referred back to "'reasons set forth in [the] Answer'" in order to set out the basis for that assertion. *Id.* (citation omitted); Answer and Counterclaim, *Joao Bock Transaction Sys., LLC v. Jack Henry & Assocs., Inc.*, Civil Action No. 12-1138-SLR, (D.I. 6), at ¶ 33 (D. Del. Dec. 3, 2012) ("*Joao Bock* Answer and Counterclaim"). In that earlier portion of the Answer, in turn, the defendant had explicitly articulated, *specifically as to the '003 patent that was at issue in the counterclaim*: (1) the particular statutory sections that were relevant to its invalidity claims; and (2) a clear description of the type of invalidity claim at issue that related to each of those statutory sections. *Joao Bock*, 292 F.R.D. at 170; *Joao Bock* Answer and Counterclaim, at ¶¶ 20-21.[8] The Answer also included at least some additional factual allegations that, taken together

[8] The Answer in *Joao Bock* did at times refer to a prior litigation between the parties involving a related patent owned by the plaintiff ("the related patent"), in order to flesh out the factual basis for its invalidity counterclaim as to the '003 patent. But to the extent it did so, the Answer specifically explained how any invalidity arguments that were asserted in the prior case as to the related patent were said to apply to the invalidity counterclaim claim at issue in instant matter involving the '003 patent. *See, e.g.*, *Joao Bock* Answer and Counterclaim, at 1-2 (noting in the Answer how the '003 patent and the related patent contained claims worded nearly the same and shared the same priority date, specification, description and drawings, and further identifying certain prior art that was at issue in the related patent litigation that was now asserted

with the content of the patent-in-suit, rendered the invalidity counterclaim plausible. *Joao Bock*, 292 F.R.D. at 168-70; *Joao Bock* Answer and Counterclaim, at 1-2 & ¶¶ 1, 9, 20, 21, 23, 24, 33. This is all more than Defendants have done here.

For these reasons, the Court recommends that Plaintiffs' Motion to dismiss Counts 6, 8 and 10 be GRANTED (that is, that this is an additional basis on which Counts 6 and 8 should be dismissed, and the only basis on which Count 10 should be dismissed).

C. Whether Claim 11 Should Be Dismissed For Failure to Allege an Interference-in-fact

Lastly, Plaintiffs assert that Count 11 should also be dismissed pursuant to Rule 12(b)(6) for failure to state a claim. (D.I. 14 at 17-19; D.I. 19 at 10) The gist of this argument is as follows: Plaintiffs first assert that a "threshold pleading requirement in any Section 291 action/priority determination is that the subject matter of the two patents [here, Defendant Gilead Pharmasset LLC's '322 patent and Plaintiffs' '600 patent] are interfering." (D.I. 14 at 18) Next, Plaintiffs note, (*id.*), that in the paragraphs comprising Count 11, Gilead Pharmasset LLC does not, in fact, assert that it believes this to be the case; instead, it alleges only that "*Counterclaim defendants* [i.e., Plaintiffs] *assert* that an interference-in-fact exists between one or more claims of the '600 patent and the '322 patent[.]" (D.I. 9 at 29 at ¶ 116 (emphasis added); *see also id.* at ¶ 115) Plaintiffs move to dismiss Count 11 pursuant to Rule 12(b)(6), on the grounds that Defendants "apparently do[] not want to concede such an interference-in-fact exists" and thus have not "affirmatively ple[d] that an interference-in-fact exists between these two patents." (D.I. 14 at 18-19)

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to be relevant to the invalidity allegations in the instant case).

For its part, Gilead Pharmasset LLC confirmed in its briefing that, for purposes of Count 11, it is "rely[ing] on Idenix's allegation [made in Count II of the Complaint in this case] that the '322 patent and the '600 patent claim the same or substantially the same subject matter, and therefore interfere[.]" (D.I. 17 at 20) Similarly, at oral argument, its counsel acknowledged that at this stage, Gilead Pharmasset LLC could not conclude or affirmatively assert facts to support the conclusion that an interference-in-fact existed. (Tr. at 87-88)[9]

There is really no dispute that a required element of a Section 291 interference action is that the two patents at issue claim the same or substantially the same subject matter. Section 291 states that the "owner of a patent may have relief by civil action against the owner of another patent that claims the same invention and has an earlier effective filing date, if the invention claimed in such other patent was derived from the inventor of the invention claimed in the patent owned by the person seeking relief under this section." 35 U.S.C. § 291. And our Court has explicitly held that in order to "sufficiently ple[a]d the prerequisites for an interference action" pursuant to Section 291, a party must affirmatively "allege[,]" *inter alia*, that "(1) [it] owns [one of the patents-at-issue]; (2) [the opposing party] owns [the other patent at issue]; and (3) [the patents at issue] *claim the same or substantially the same subject matter and, therefore, interfere*[.]" *Bayer Intellectual Prop. GMBH v. Warner Chilcott Co., LLC*, Civil Action No. 12-1032-GMS, 2013 WL 6503456, at *3 (D. Del. Dec. 9, 2013) (emphasis added) (resolving a

[9] Defendants' counsel explained that Defendants had nevertheless brought Count 11 because it wished to have some control over how and whether the Section 291 issue is ultimately litigated. (Tr. at 89)

motion to dismiss an interference claim pursuant to Rule 12(b)(1))[10]; *see also Datex-Ohmeda, Inc. v. Hill-Rom Servs., Inc.*, 185 F. Supp. 2d 407, 410-11 (D. Del. 2002) (same).

Thus, the only issue is whether Defendants' failure to allege that this element is met (and set out facts supporting why it believes this is so) is fatal pursuant to Rule 12(b)(6). The Court cannot conceive of a circumstance in which a party could be said to have met its burden to state a claim—not by affirmatively asserting that facts exist that would plausibly satisfy a claim element—but instead by contending only that *someone else* thinks that they do. *See Twombly*, 550 U.S. at 555 (noting that the party asserting a claim bears the "obligation" to make plausible factual "allegations" that, if assumed true, suffice to state a claim); *see also* Fed. R. Civ. P. 8 (noting that a claim for relief must include a short statement of the claim "showing that the pleader is entitled to relief"); Fed. R. Civ. P. 13. When asked during oral argument, neither could Defendants. (Tr. at 91)

Because Count 11 does not affirmatively assert that a necessary element of a Section 291 claim exists, nor that there are facts to support its existence, it fails to state a claim pursuant to Rule 12(b)(6). Thus, the Court recommends that Plaintiffs' Motion as to this claim be GRANTED.

III. CONCLUSION

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[10] Indeed, in *Bayer*, the plaintiff, who was asserting the interference claim at issue, did in fact affirmatively plead in that Count that "[a]t least the following claims of the [two patents at issue] are interfering in that they both claim the same or substantially the same subject matter, specifically a contraceptive regimen as [previously referred to in the Complaint's earlier factual allegations]" and then proceeded to set out a list of the claims of the respective patents that were alleged to interfere with each other. First Amended Complaint, *Bayer Intellectual Prop. GMBH v. Warner Chilcott Co., LLC*, Civil Action No. 12-1032-GMS (D.I. 5), at ¶ 26 (D. Del. Dec. 18, 2012) (cited in *Bayer*, 2013 WL 6503456, at *3).

For the foregoing reasons, the Court recommends that Plaintiffs' Motion should be GRANTED as to each of the issues (and Counts) referenced above. As it is within the Court's discretion to grant leave to amend, *see Foman v. Davis*, 371 U.S. 178, 182 (1962), because amendment should be allowed "when justice so requires[,]" Fed. R. Civ. P. 15(a)(2), and because it is not clear that amendment would cause undue prejudice or would be futile (nor have Plaintiffs explicitly contended that it would), the Court recommends that Defendants be given leave to file an amended complaint addressing the deficiencies outlined above. *See, e.g.*, *Pragmatus AV, LLC v. Yahoo! Inc.*, C.A. No. 11-902-LPS-CJB, 2013 WL 2295344, at *2 (D. Del. May 24, 2013).

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The failure of a party to object to legal conclusions may result in the loss of the right to *de novo* review in the district court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878–79 (3d Cir. 1987).

The parties are directed to the Court's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the District Court's website, located at http://www.ded.uscourts.gov.

Dated: August 25, 2014

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE